

QRS Office Hours

Dana Booth, Sr. Project Manager & QRS Co-Lead, CDISC

Diane Corey, Data Manager & Standards Expert, Critical Path Institute

Rachel Dlugash, Statistician, FDA

Steve Kopko, Subject Matter Expert & Consultant, CDISC

Barbara Lentz, Standards Engineer, IQVIA

Dr. Jordan Li, Terminology Expert, National Cancer Institute's Enterprise Vocabulary Services (NCI EVS)

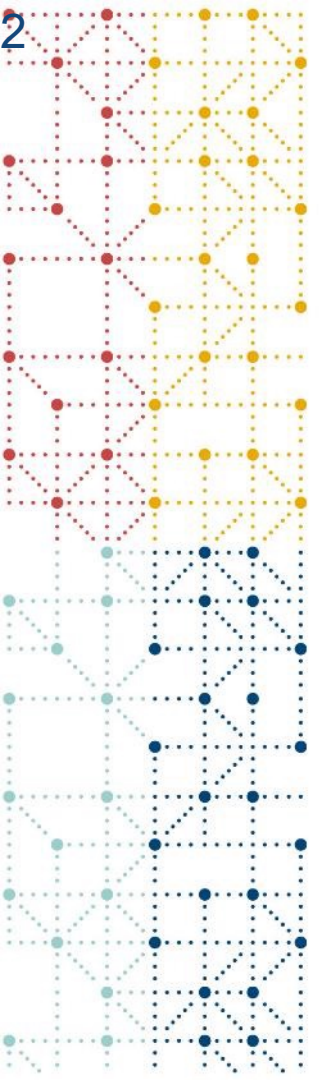
Dr. Sandra Mitchell, Senior Scientist and Program Director, National Cancer Institute

Dr. Liping Sun, Statistician, FDA

Dr. Steve Wilson, Senior Staff Fellow, FDA

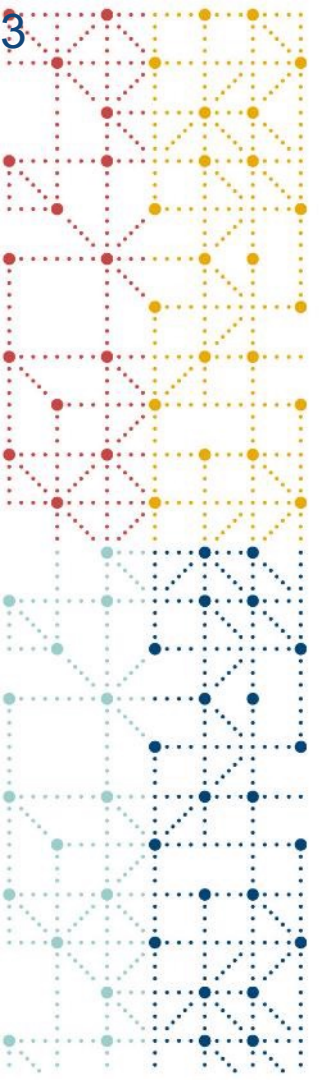


Thursday, 8 September
11:00AM – 12:30PM US ET



Today's Agenda

1. Housekeeping
2. Speaker Introduction
3. Feature Presentation
4. Upcoming Learning Opportunities & Events



Housekeeping

Housekeeping



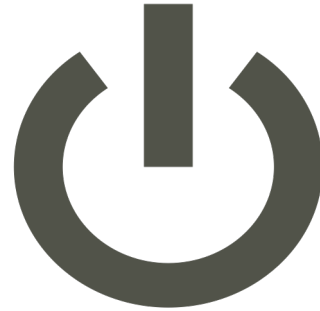
You will remain on **mute**

Housekeeping



Submit questions at any time via the
Questions tool on your Zoom app

Housekeeping



Audio Issues?

First, close and restart your Zoom App
Second, check your local internet connection strength

Housekeeping



A recording of this webinar and the slides will be available in the **Public Webinar Archive**. Check under the “Events” tab on the CDISC homepage.

Our Presenters

<p>Dana Booth Sr. Project Manager & QRS Co-Lead CDISC</p>	<p>Diane Corey Data Manager & Standards Expert Critical Path Institute</p>
<p>Rachel Dlugash Statistician FDA</p>	<p>Steve Kopko Subject Matter Expert & Consultant CDISC</p>
<p>Barbara Lentz Standards Engineer IQVIA</p>	<p>Dr. Jordan Li Terminology Expert National Cancer Institute's Enterprise Vocabulary Service</p>
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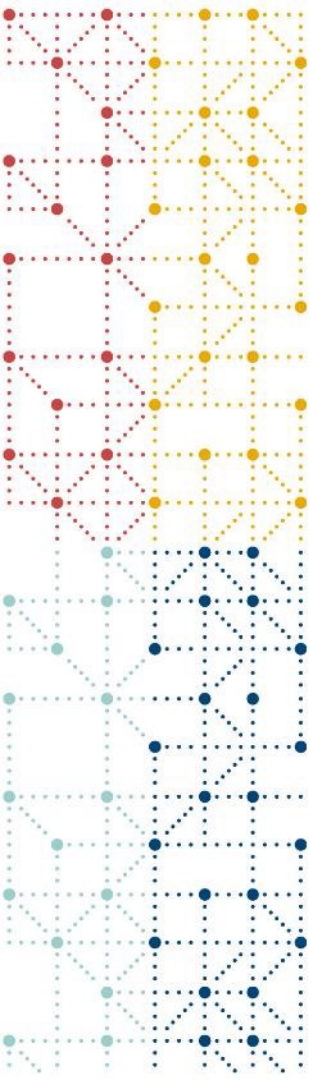
Agenda

QRS/ADQRS Publication updates: [New QRS Supplements](#)

- 3Q22 QRS Supplement Publication 30-Aug-22
- Review Public/Internal/Team supplement review lists
 - Includes 1st Disease Response supplement – RECIST V 1.1
- Review instruments in FDA review
- Important instruments in development – Quality Metrics instruments, FACIT instruments, PRO-CTCAE, PROMIS
- Review QRS webpage Resources Tab

CDISC is seeking volunteers to develop QRS supplements under the QRS subteam guidance

- <https://www.cdisc.org/volunteer>

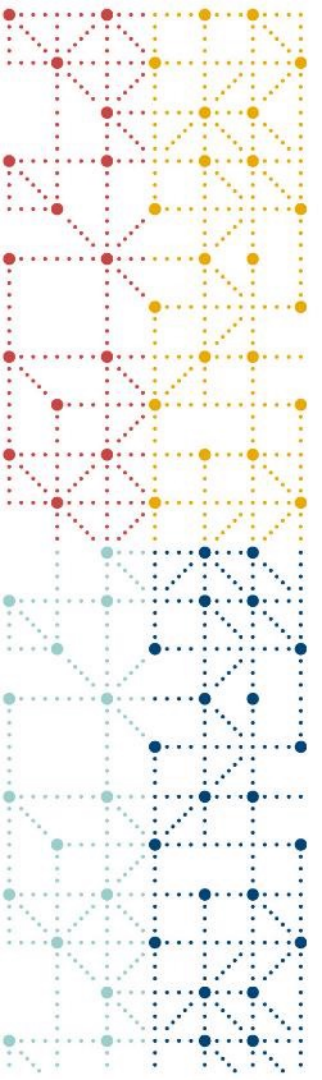


Thank You!

THE CDISC QRS Subteam WANTS YOU to volunteer !!!



cdisc



Questions & Answers

Audience Questions



We use SDTMIG 3.2 but would adopt datasets (FT, RE) and new variable like LBLOBXFL from SDTMIG 3.3. Any instruction?

Audience Questions

How can I learn how to standardize a published instrument that CDISC hasn't standardized but I need for my study?



Audience Questions



How can I judge if the questionnaire needs a license?

Audience Questions

If a trial changes anything on a questionnaire can the CDISC CAT still be used or do we need a unique but similar sponsor CAT?



Audience Questions



How can Novartis contribute to this efforts? We are working on developing standards around QRS.

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Audience Questions



The CDSIC Fatigue Severity Scale (FSS) questionnaire has 9 questions and FSS01TC & FSS01TN are non-extensible codelists in the controlled terminology. In my company we are collecting 10 questions, whereas 10th question is 'Please indicate on the line below how severe your fatigue has been in the past xx weeks' is related to VAS scale having measurements NO FATIGUE to FATIGUE AS BAD AS COULD BE. Since FSS01TC & FSS01TN are non-extensible codelist. Let me know how we can handle it.

Audience Questions

Do you have (or expect to get) permission to develop ADQRS supplements for SF36, FACIT, PRO-CTCEA and PROMIS?



Audience Questions

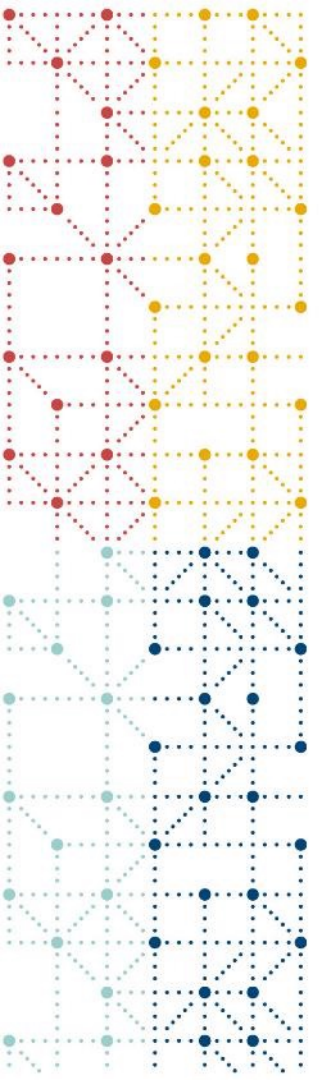


How to annotate a questionnaire for which you do not have reference in the CDISC or at the sponsor. Are there any instructions on these to follow, can such questionnaires be raised as request to CDISC, if yes where?

Audience Questions

How can I assess the questionnaire is in a public domain? and how can I confirm if the document needs a license or not?





Upcoming Events

September

US



Virtual Training Event

- Information available at: www.cdisc.org
- Register at: <https://learnstore.cdisc.org/>
- Contact us at: training@cdisc.org



BLEND
ED LEARNING



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TRAINING



CLASSROOM
TRAINING



PRIVATE
TRAINING

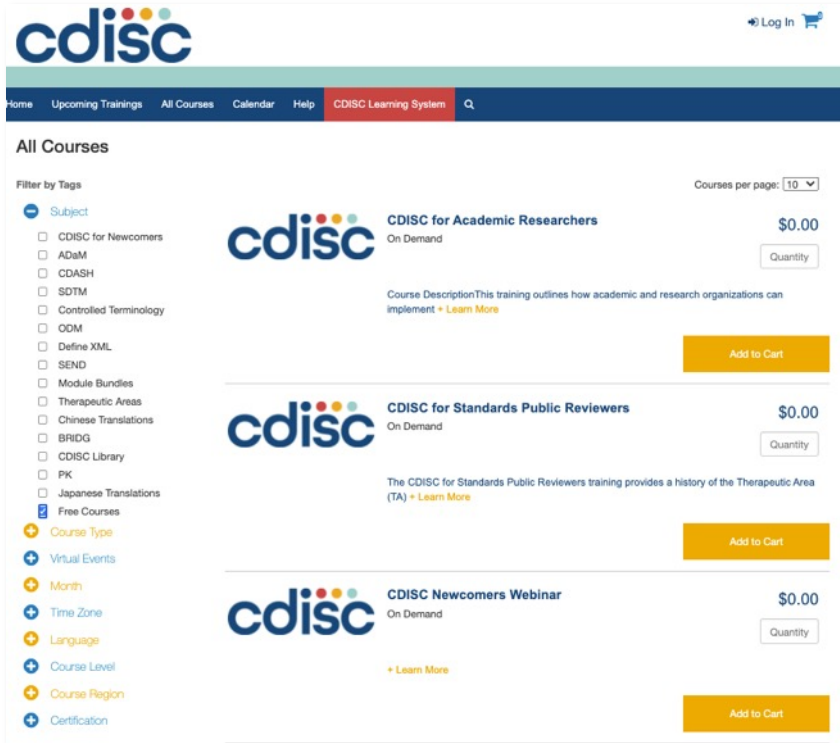


WEBINARS



WORKSHOPS

Free CDISC Courses



The screenshot shows the CDISC Learning System website. The top navigation bar includes links for Home, Upcoming Trainings, All Courses, Calendar, Help, and CDISC Learning System. The main content area is titled "All Courses" and features a "Filter by Tags" section on the left with various categories like Subject, Course Type, Virtual Events, Month, Time Zone, Language, Course Level, Course Region, and Certification. The "Subject" filter is expanded, showing a list of checkboxes for various CDISC topics. Three course cards are displayed, each with the CDISC logo, title, "On Demand" status, a price of "\$0.00", a "Quantity" input field, and an "Add to Cart" button. The courses are: "CDISC for Academic Researchers", "CDISC for Standards Public Reviews", and "CDISC Newcomers Webinar".

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Home Upcoming Trainings All Courses Calendar Help **CDISC Learning System** Q

All Courses

Filter by Tags Courses per page: 10

- Subject
 - CDISC for Newcomers
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 - Controlled Terminology
 - ODM
 - Define XML
 - SEND
 - Module Bundles
 - Therapeutic Areas
 - Chinese Translations
 - BRIDG
 - CDISC Library
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 - Free Courses
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The CDISC for Standards Public Reviews training provides a history of the Therapeutic Area (TA) + Learn More

cdisc **CDISC Newcomers Webinar** \$0.00
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[Http://learnstore.cdisc.org](http://learnstore.cdisc.org)

Upcoming Webinars

Date	Title
13 SEP	TFL Designer Virtual Workshop
27 SEP	CORE Volunteer Onboarding Training
29 SEP	COSA Spotlight Q3
4 OCT	Controlled Terminology Updates: P51 Publication / P52 Public Review
18 OCT	CORE Volunteer Onboarding Training
20 DEC	Controlled Terminology Updates: P52 Publication / P53 Public Review

Do you have a suggestion or idea for a webinar topic you'd like us to cover?

<https://www.cdisc.org/form/webinartopicreq>

2022 CDISC US Interchange

Austin, TX, 26-27 October



CDISC Events, 2023



Thank you!



Contact the Events inbox:
events@cdisc.org



Contact Education inbox:
training@cdisc.org



Contact Bernard directly:
bklinke@cdisc.org